California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
EDMUND G. BROWN JR., GOVERNOR

Date: **July 21, 2011**

To: **Enforcement Committee**

Subject: **Agenda Item 1- Exemptions Requested from Patient-Centered Labeling Requirements**

Attachment 1

Status:
At the May Board Meeting, the board tabled the discussion of request from the California Pharmacists Association for an exemption from the requirements for patient-centered labels for medications dispensed to patients in skilled nursing facilities. The board directed the committee to continue its discussion at the next Enforcement Committee Meeting. This is that meeting.

Background:

Effective January 1, 2011, the board's requirements for patient-centered labels went into effect as 16 California Code of Regulations section 1707.5. A copy of the final text for the regulation is provided in **Attachment 1**.

Also effective January 1, 2011, amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments. The exemptions are provided as subdivisions (d) and (e) below.

> SEC. 25.1. Section 4076.5 of the Business and Professions Code is amended to read:
>
> 4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.
> (b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.
> (c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:
> (1) Medical literacy research that points to increased understandability of labels.
> (2) Improved directions for use.
> (3) Improved font types and sizes.
> (4) Placement of information that is patient-centered.
> (5) The needs of patients with limited English proficiency.
> (6) The needs of senior citizens.
> (7) Technology requirements necessary to implement the standards.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code. if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.
(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
(C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.
(f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report. (2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

This law directs that the board "may exempt," so to allow an exemption, the board would need to promulgate regulations.

At the December 2010, March and July 2011 Enforcement Committee Meetings, the committee heard presentations from groups seeking exemption from the labeling requirements for their specialized patient populations. The board has not yet approved a waiver request.

The committee has directed that any exemption request include at least: 1. an explanation as to why the company cannot comply with the new requirements and 2. information regarding policies or procedures in place that address the policy concerns behind the adopted regulations.

<u>At this Meeting:</u>

At this meeting, the board will continue its discussion with pharmacy representatives who serve skilled nursing facilities that seek an exemption to labeling requirements for medication dispensed to patients in skilled nursing facilities.

The specific issue before the committee and board now focuses on: the skilled nursing facility will receive medication that is labeled for a specific patient, in the patient-centered format in 10 point font. However, the exemption sought is that the labeling would not be converted to 12 point font -- even upon patient request -- if the remaining medication is sent home with a discharged patient.

An excerpt from the minutes of the May Board Meeting is provided in **Attachment 1**.

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Date: **July 21, 2011**

To: **Enforcement Committee**

Subject: **Agenda Item 2: Consider Recommendations by the Committee to Amend the Board's Disciplinary Guidelines at 16 California Code of Regulations Section 1760, Including to Incorporate Recommendations of the Substance Abuse Coordination Committee (Pursuant to SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008)**

Attachments 2 and 3

Background

The board has initiated a restructuring and updating of its Disciplinary Guidelines. To incorporate changes to the Disciplinary Guidelines, the board needs to initiate a rulemaking.

As part of this effort, the board has also determined to incorporate the recommendations of the DCA's Substance Abuse Coordination Committee into the Disciplinary Guidelines.

As you may remember, Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. To facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for SACC consideration during public meetings. There are 16 standards that were developed.

The most recent version of the SACC standards was approved in April 2011. **Attachment 2** contains a copy of the standards in their current form.

In March 2011, a board subcommittee of Stan Weisser and Tappan Zee met in a first step toward incorporating these standards into the Disciplinary Guidelines.

At the May board meeting, the board directed staff to develop regulatory language to modify the disciplinary guidelines to incorporate the SB 1441 standards.

Attachment 3 contains the proposed changes that have been identified and drafted for board consideration for incorporation into the board's Disciplinary Guidelines. This will be the major discussion document for this section of the committee meeting.

To ensure the relevance, integrity and value of the Disciplinary Guidelines, Deputy Attorney General Joshua Room has developed the draft of the Disciplinary Guidelines, incorporating three levels of changes (reorganization, Uniform Standards, Board Subcommittee).

It is important to note that several of the Uniform Standards do not fit within this framework and are more policy standards and/or standards of general application, rather than terms that must be negotiated as part of settlement.

The committee/ board needs to also discuss these items and determine how it wishes to proceed. Specifically:

- Uniform Standard # 6, which sets up factors the board should consider in deciding whether to send a respondent to inpatient, outpatient, or other type of treatment. The Disciplinary Guidelines do not currently have a term whereby the Board can send a respondent to treatment (PRP handles that, for those in PRP).
- Uniform Standard # 9, which defines a failed drug test as a major violation.
- Uniform Standard # 10, which defines major and minor violations.
- Uniform Standard # 11, which defines the criteria that must be met before a respondent can petition to return to full-time practice.
- Uniform Standard # 12, which defines the criteria that must be met before a respondent can "petition for reinstatement" to an unrestricted license (but is specifically defined as not the APA's petition for reinstatement in the Uniform Standards).
- Uniform Standard # 13 defines standards and specifications for contracts with and requirements of drug testing vendors/contractors.
- Uniform Standard # 14 defines what information about respondents/licensees who are in a diversion program (PRP) shall be publicly disclosed.
- Uniform Standard # 15 sets up auditing requirements for diversion services vendors.
- And Uniform Standard # 16 sets up board reporting requirements to the Legislature.

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Date: **July 21, 2011**

To: **Enforcement Committee**

Subject: **Agenda Item 3-** Review and Discussion of Enforcement Statistics and Performance Standards of the Board

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20010/11 enforcement statistics for the board's enforcement efforts are provided on the following pages.

PATIENT-CENTERED LABEL REQUIREMENTS:

1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements
(a) Labels on drug containers dispensed to patients in California shall conform to the following format:
(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-pooint typeface, and listed in the following order:
(A) Name of the patient
(B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.
(C) The directions for the use of the drug.
(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
(4) When applicable, directions for use shall use one of the following phrases:
(A) Take 1 [insert appropriate dosage form] at bedtime
(B) Take 2 [insert appropriate dosage form] at bedtime
(C) Take 3 [insert appropriate dosage form] at bedtime
(D) Take 1 [insert appropriate dosage form] in the morning
(E) Take 2 [insert appropriate dosage form] in the morning
(F) Take 3 [insert appropriate dosage form] in the morning
(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening
(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
(L) Take 3 [insert appropriate dosage form] in the morning, 3 insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day
(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
(c) Beginning in October 2011the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. If interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.
(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.
(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

Excerpt of Board of Pharmacy Meeting Minutes, May 3, 2011:

Request 3: From CPhA's Long-Term Care Academy for Skilled Nursing Facilities

Dr. Kajioka provided that the committee had a detailed discussion with CPhA long-term care members about the method of drug distribution within skilled nursing facilities (SNFs), continuing discussions started at the prior Enforcement Committee and February 2011 Board Meeting. He stated that of particular concern to the committee was that if the exemption were provided to pharmacies dispensing drugs to skilled nursing facilities, how will the pharmacies, particularly those dispensing medications in the bingo cards that are often used in SNFs, be able to ensure that these discharged patients can readily read the labels when they leave the facility.

Dr. Kajioka provided that the labels must adhere to the labeling requirements if there is any opportunity for the medication to go home with the patient.

Dr. Kajioka provided that when reviewing the bingo-type cards in use in SNFs, the committee generally concluded that these cards should be labeled according to the patient-centered requirement because they are potentially likely to be taken home with patients because they may contain a seven or 30 day supply of drugs. He stated that the committee noted that there appears to be adequate space on the bingo cards to label the product according to the patient-centered requirements.

Dr. Kajioka provided that the committee agreed that unit-dose medications dispensed via an automated dispensing machine in SNFs could be exempt from the patient-centered labeling requirements.

Dr. Kajioka reviewed the motion from the committee to recommend an exemption to the patient-centered label requirements for unit dose medications dispensed via an automated dispensing machine in SNFs pursuant to Business and Professions Code section 4076.5(d).

Discussion
Ms. Shellans clarified that the exemption is being sought for unit-dose medications that are administered to the patient by a licensed healthcare professional.

The board discussed the committee's recommendation in light of the request. Concern was expressed that the recommendation does not specify that the exemption is specifically for medication that will not go home with the patient. The board asked for clarification on CPhA's request.

Mr. Room clarified that CPhA's initial request was for an exemption for all medications dispensed by a pharmacy to a SNF. He indicated that the committee felt that the request was only appropriate for unit-dose medication that would not go home with the patient.

Stan Goldenberg, representing CPhA, and Scott Hahn, representing Omnicare, provided an overview of emergency medications dispensed in SNFs. He discussed that this medication, usually a unit-dose, can come from an automated system or an e-kit. Mr. Goldenberg clarified that in both cases, no medication will go home with the patient. He also provided comment regarding new technology that pre-pours medications, as programmed by the contracting pharmacy, into an envelope to be administered by nursing staff to patients. Mr. Goldenberg stated that the envelopes are labeled to the patient according to the labeling laws previous to the patient-centered label regulation.

Mr. Goldenberg provided that the labels on bingo cards will be in a 10-point font, in compliance with the regulation. He discussed that the committee indicated that the patient can request a 12-point font at the time of the next refill post discharge from a SNF. He requested that, in the event the exemption is granted, the next issue of *The Script* include an article to clarify the exemption for the industry.

Mr. Room discussed two legally defensible possibilities regarding dispensing: (1) dispensing to the patient happens only once during the initial dispensing or (2) dispensing to the patient happens when the patient has an opportunity to comment on the dispensing transaction. He recommended that the board clarify what it considers a dispensing transaction to be by way of regulation.

Mr. Goldenberg discussed additional challenges with the overlay of new federal and insurance requirements that require dispensing in smaller doses. He also discussed the need for uniformity in labeling for licensed staff and the challenges faced with the relabeling of medication prior to discharge.

Board Member Deborah Veale cautioned the board from overanalyzing this issue. She reiterated that bingo cards will be dispensed with a label in a 10-point font and the patient will have the opportunity to request a 12-point font at the time of the next refill.

Board Member Ramón Castellblanch discussed that the population being discharged from SNFs are at a greater need for understanding and reading the information on the label. He provided that any medication that could go home with the patient, including bingo cards, should comply with the requirements of the regulation.

Mr. Goldenberg provided comment regarding patient discharge from SNFs and indicated that requiring relabeling of medication in a 12-point font prior to

discharge will result in significant delays. He discussed that requiring a 12-point label for all medications would result in larger, costly packaging and would disrupt the established systems inside SNFs to ensure that patients receive the appropriate medication.
Dr. Castellblanch provided that the pharmacy industry has expressed similar concern; yet, is complying with the requirements. He expressed concern regarding the board's jurisdiction with regards to discharge in nursing homes and suggested that the board hear input from nursing home advocates on this issue.

Mr. Room discussed the board's limited authority under section 4076.5(d) which states that the board may not exempt prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility. He stated that the only way the requirement for 12-point font upon request will not be required is if the board determines that dispensing only occurs at the time of the initial dispensing and the request for 12-point font can be ignored. Mr. Room indicated that this is an interpretation, not an exemption.

President Weisser encouraged the board to consider what interpretation is in the best interest of the patient. He discussed that patient protection could be compromised if it is determined that no medications can go home at discharge.

Discussion continued. Concern was expressed regarding ownership of the medication while the patient is in a SNF and possible unintended consequences in the event the medication is withheld.

Ms. Shellans provided that regulations will need to be promulgated before any exemption can be granted. She stated that this discussion will be used for development of such regulations.

Dr. Kajioka suggested that this issue be returned to the Enforcement Committee for further review.

MOTION: Table action on the recommendation from the Enforcement Committee.

M/S: Schell/Lippe

Support: 10 Oppose: 0 Abstain: 0

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Dr. Kajioka suggested that this issue be returned to the Enforcement Committee for further review.

MOTION: Table action on the recommendation from the Enforcement Committee.

M/S: Schell/Lippe

Support: 10 Oppose: 0 Abstain: 0

Potential Revisions to Disciplinary Guidelines to Incorporate
SB 1441 Uniform Standards and Staff Proposals[1]

Changes in blue reflect the Uniform Standards (green is used for subcommittee edits)

Changes in red reflect staff proposals that may have predated the Uniform Standards

18. ~~**Mental Health Examination**~~ **Clinical Diagnostic Evaluation**[2] (Appropriate for those cases where evidence demonstrates that mental illness, substance abuse, or disability was a contributing cause of ~~the~~ a violation or violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter if ~~as may be~~ required by the board or its designee, respondent shall undergo, at his or her own expense, ~~psychiatric~~ clinical diagnostic evaluation(s) by a ~~board-appointed or board-approved~~ licensed ~~mental health~~ practitioner selected or approved prior to the evaluation by the board or its designee. The approved evaluator shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a ~~pharmacist~~ [pharmacist, pharmacy technician, or designated representative] with safety to the public. ~~Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.~~ If the evaluator recommends restrictions or conditions on respondent's practice, including but not limited to other terms and conditions listed in these guidelines (e.g., required psychotherapy, prescription coordination and monitoring, restricted practice), the board or its designee may by written notice to respondent adopt these restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.

~~If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.~~

[1] This document is limited to those terms and conditions in the Disciplinary Guidelines that would be affected by the SB 1441 Uniform Standards. For those, it shows both the proposed changes necessary to conform to the SB 1441 Uniform Standards and the changes separately proposed by staff. There are other terms and conditions where staff have proposed changes that are not included here, because this discussion is focused on the Uniform Standards.

[2] The changes to this term are those necessary to make it consistent with Uniform Standards # 1 and # 2.

~~Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.~~

~~Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.~~

~~If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently as a pharmacist, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.~~

Option #1 (mandatory in all cases involving alcohol or substance abuse): The evaluation(s) shall be conducted in accordance with acceptable professional standards for alcohol or substance abuse clinical diagnostic evaluations. The written report(s) shall set forth, at least, the opinions of the evaluator as to: whether respondent has an alcohol or substance abuse problem; whether respondent is a threat to him/herself or others; and recommendations for alcohol or substance abuse treatment, practice restrictions, or other steps related to respondent's rehabilitation and safe practice. If the evaluator determines during the evaluation process that respondent is a threat to him/herself or others, the evaluator shall notify the board within twenty-four (24) hours.

Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [pharmacist, pharmacy technician, or designated representative] until:

- Respondent has undergone and completed clinical diagnostic evaluation(s);
- The report(s) of the evaluation(s) has/have been received by the board or its designee;
- One or more report(s) has concluded that respondent is safe to return to practice as a [pharmacist, pharmacy technician, or designated representative];
- Respondent has submitted to observed bodily fluid testing for the presence of alcohol, dangerous drugs, or controlled substances [pursuant to Term and Condition ??] ~~at least twice per week~~ for at least thirty (30) days;
- During the testing period, respondent has not had a confirmed positive test result for alcohol, or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment, ~~for at least thirty (30) days~~;

- The board or its designee has determined that respondent is safe to return to either full-time or part-time practice as a [pharmacist, pharmacy technician, or designated representative], after considering the evaluation report(s), the results of the fluid testing, and criteria including the license type, respondent's history, respondent's documented period of sobriety or documented time since last use, respondent's scope and pattern of use, respondent's treatment history, respondent's medical history and current medical condition, the nature, duration, and severity of respondent's alcohol or substance abuse, and whether respondent is a threat to him/herself or others; and
- Respondent receives written notice that practice may resume.

[Staff propose moving this paragraph from the guidelines to the form used to select evaluators:] The board or its designee shall select or approve evaluator(s) holding a valid, unrestricted license to practice, with a scope of practice that includes the conduct of clinical diagnostic evaluations and at least three (3) years experience conducting such evaluations of health professionals with alcohol or substance abuse problems. The evaluator(s) shall not have a financial relationship, personal relationship, or business relationship with respondent within the last five (5) years. The evaluator(s) shall provide an objective/ unbiased, and independent evaluation of respondent.

For all such evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator ~~is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.~~ completes the evaluation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices.

Option #2 (optional in all other cases): Commencing on the effective date of this decision, respondent is suspended from practice and shall not ~~engage in the practice of pharmacy~~ practice as a [pharmacist, pharmacy technician, or designated representative] until ~~notified in writing by the board that respondent has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation~~ the evaluator recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice that practice may resume.

The final written report of the evaluation shall be provided to the board no later than ten (10) days from the date the evaluator ~~is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.~~ completes the evaluation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this suspension shall be considered a violation of probation.

~~(Option language to be used in addition to standard language)~~

Option #3 (optional in all other cases): If recommended by the ~~evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until respondent's treating therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.~~ evaluator, the board or its designee may suspend respondent from practice as a [pharmacist, pharmacy technician, or designated representative] by providing written notice of suspension. Upon suspension, respondent shall not resume practice as a [pharmacist, pharmacy technician, or designated representative] until another evaluation done at respondent's expense by a licensed practitioner selected or approved by the board or its designee recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice that practice may resume.

The report(s) from any such additional evaluation(s) shall be provided to the board no later than ten (10) days from the date the evaluator ~~is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.~~ completes the evaluation.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs

~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

NEW TERM & CONDITION (applicable in cases involving alcohol or substance abuse):

??. Reporting of Employment; Consent.[3] Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of all of [his/her] employer(s), and the name(s) and telephone number(s) of all of [his/her]direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, or other compliance supervisor(s). Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

22. ~~Random Drug Screening~~ Drug and Alcohol Testing[4] (~~If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required~~ Mandatory in all cases involving alcohol or substance abuse; may be combined with PRP.)

Respondent, at ~~his or her~~ [his/her] own expense, shall participate in random testing~~, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program~~ as directed by the board or its designee~~. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the~~

[3] This term would comply with Uniform Standard # 3.

[4] This term would comply with Uniform Standard # 4.

board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnoticscontrolled substances, and dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate in a timely fashion shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day. Though the frequency of testing will be determined by the board or its designee, and shall be designed so as to prevent respondent from anticipating testing dates (either randomized testing or unpredictable dates), the frequency of testing shall be at least the following: at least fifty-two (52) test dates during the first year of probation; at least thirty-six (36) test dates during the second, third, fourth, and fifth years of probation; and at least one (1) test per month in each year of probation after the fifth so long as there have been no positive test results during the previous five (5) years.The board or its designee may require less frequent testing if any of the following applies:

- Where respondent has previously participated in a treatment or monitoring program requiring testing, the board or its designee may consider that prior testing record in applying the three-tier testing frequency schedule described above;
- Where the basis for probation or discipline is a single incident or conviction involving alcohol or drugs, or two incidents or convictions involving alcohol or drugs that were at least seven (7) years apart, that did not occur at work or on the way to or from work, the board or its designee may skip the first-year testing frequency requirement(s);

- ~~Where respondent is not employed in any health care field, frequency of testing may be reduced to a minimum of twelve (12) tests per year. If respondent wishes to thereafter return to employment in a health care field, respondent shall be required to test at least once a week for a period of sixty (60) days before commencing such employment, and shall thereafter be required to test at least once a week for a full year, before [he/she] may be reduced to a testing frequency of at least thirty-six (36) tests per year, and so forth;~~
- ~~Respondent's testing requirement may be suspended during any period of tolling of the period of probation;~~
- ~~Where respondent has a demonstrated period of sobriety and/or non-use, the board or its designee may reduce the testing frequency to no less than twenty-four (24) tests per year.~~

Any detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, may cause the board or its designee to increase the frequency of testing, in addition to any other action including but not limited to further disciplinary action.

Prior to any vacation or other period of absence from the geographic area of the approved testing vendor, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor in the geographic area to be visited or resided in by respondent. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide that alternate vendor with any necessary information and documentation, including any necessary for payment by respondent. During the period of visitation or residence in the alternate geographic area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection through testing of a controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [pharmacist, pharmacy technician, or designated representative] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or

its designee shall inform respondent of the suspension and inform [him/her] to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.[5]

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

[Staff propose including these elements of Uniform Standard # 4 in the testing vendor contract]: The board may be required to report data to support testing on consecutive days as well as numerous different testing intervals, and shall require cooperation from the vendor to do so.

Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered. Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The

[5] This blue text incorporates a modified form of Uniform Standard # 8, though it reverses the order of events. The Board's existing language permits a suspension only after a respondent fails to supply a prescription or some other documentation justifying a positive result. Uniform Standard # 8 calls for the suspension to be immediate upon the detection of a "banned substance," after which it can be lifted upon documentation of a legitimate prescription. The language included here also does not explicitly incorporate the language in Uniform Standard # 8 mandating that in investigating a positive test result, Board staff consult with the specimen collector and the laboratory, communicate with respondent and/or his/her physician, and speak with any treatment provider, including group facilitators.

appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

The board will be required to collect and report historical and post implementation data on testing as follows, and shall require cooperation from the vendor to do so:

For the two-year period prior to implementation of the Uniform Standards, the board shall collect and report data (as available) for each person subject to testing who has (1) tested positive for a banned substance, (2) failed to appear or call in for testing on more than three occasions, (3) failed to pay testing costs, or (4) given a dilute(d) or invalid specimen.

For a period of three years following implementation of the Uniform Standards, the board shall collect and report the data including but not limited to the following to the Department of Consumer Affairs and/ upon request, to the Legislature:

Probationer/Diversion Participant Unique Identifier
License Type
Probation/Diversion Effective Date
General Range of Testing Frequency by/for Each Probationer/Diversion Participant
Dates Testing Requested
Dates Tested
Identify the Entity that Performed Each Test
Dates Tested Positive
Dates Contractor (if applicable) was informed of Positive Test
Dates Board was informed of Positive Test
Dates of Questionable Tests (e.g. dilute, high levels)
Date Contractor Notified Board of Questionable Test
Identify Substances Detected or Questionably Detected
Dates Failed to Appear
Date Contractor Notified Board of Failed to Appear
Dates Failed to Call In for Testing
Date Contractor Notified Board of Failed to Call In for Testing
Dates Failed to Pay for Testing
Date(s) Removed/Suspended from Practice (identify which)
Final Outcome and Effective Date (if applicable)

NEW TERM & CONDITION (applicable in cases involving alcohol or substance abuse):
??. Facilitated Group Recovery and/or Support Meetings.[6] Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a group recovery and/or support meeting that is run by a trained facilitator approved in advance by the board or its designee. The required frequency of group meeting attendance shall be determined by the board or its designee, after taking into consideration respondent's history, the documented length of the respondent's sobriety or time since last use, any recommendation(s) from any clinical diagnostic evaluation(s), the scope and pattern of respondent's use, respondent's treatment history, and the

[6] This term would comply with Uniform Standard # 5.

nature, duration, and severity of respondent's prior or present substance abuse. Respondent shall continue regular attendance as directed at an approved facilitated group meeting until the board or its designee advises in writing that respondent may cease regular attendance.
The facilitator shall, upon request by the board or its designee, provide the board with a dated document signed by the facilitator that includes respondent's name, the group's name, if any, the date and time of its regular meeting(s), respondent's attendance record, and respondent's participation level and progress. Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

The approved facilitator shall report any unexcused absence by respondent from a facilitated group meeting to the board within twenty four (24) hours of its occurrence.

[Again, this may be something that does not need to be in the probationary term itself]:
The board or its designee shall select or approve facilitators with at least three (3) years of experience in the treatment and rehabilitation of substance abuse, with a license or certificate from the state or other nationally certified organization. The facilitator(s) shall not have had a financial, personal, or business relationship with respondent within the last year.

18. Work Site Monitor (~~Appropriate for those cases with chemical dependency (alcohol, drugs)~~ applicable in cases involving alcohol or substance abuse)[7]
Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board ~~quarterly~~ monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor ~~determine~~ suspect at any time during the probationary period that respondent has ~~not maintained sobriety~~ abused alcohol or drugs, he or she shall notify the board immediately~~, either orally or in writing as directed~~. The initial notification shall be made orally within one (1) business day of the occurrence, and shall be followed by written notification within forty-eight (48) hours of the occurrence. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board or its designee, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board by the monitor, shall be considered a violation of probation.

The work site monitor shall not have a financial, personal, familial or other relationship with the respondent that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but respondent's employer to serve as work site monitor, this requirement may be waived by the board; however, under no circumstances shall respondent's work site monitor be respondent's employee.

[7] These modifications are intended to conform this term to Uniform Standard # 7. As written, this optional term in the Disciplinary Guidelines is currently only applicable to pharmacy technicians and designated representatives because, at least typically, pharmacists and pharmacy interns would be enrolled in PRP and PRP will require a work site monitor and control the selection and requirements of that monitor. To conform to Uniform Standard # 7, this term will need to be made more universally applicable and/or the criteria for selection of a work site monitor will need to be made applicable to those persons whose work site monitors are being selected by PRP/Maximus staff.

The work site monitor shall hold a license with a scope of practice including the scope of practice of the respondent's license, shall be another health care professional if no monitor with like practice is available, or, as approved by the board or its designee, shall be a person in a position of authority who is capable of monitoring respondent while at work.

~~If the work site monitor is a licensed healthcare professional he or she shall have an active unrestricted license, with no disciplinary action within the last five (5) years.~~

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
2) Interview other staff in the office regarding respondent's behavior, if applicable; and
3) Review respondent's work attendance.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the board to allow the board or its designee to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Option for respondents enrolled in PRP or who are given the PRP enrollment term: It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that [he/she] is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, and shall be followed by written notification within forty-eight (48) hours of the occurrence. Should respondent change employment, a new work site monitor must be designated, for prior approval by the PRP, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

The work site monitor shall not have a financial, personal, familial or other relationship with the respondent that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the PRP. If it is impractical for anyone but respondent's employer to serve as work site monitor, this requirement may be waived by the PRP; however, under no circumstances shall respondent's work site monitor be respondent's employee.

The work site monitor shall hold a license with a scope of practice including the scope of practice of the respondent's license, shall be another health care professional if no monitor with like practice is available, or, as approved by the PRP, shall be a person in a position of authority who is capable of monitoring respondent while at work.

~~If the work site monitor is a licensed healthcare professional he or she shall have an active unrestricted license, with no disciplinary action within the last five (5) years.~~

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
2) Interview other staff in the office regarding respondent's behavior, if applicable; and
3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the PRP to allow the PRP to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2010/2011

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Complaints/Investigations					
Received	583	599	643	600	2425
Closed	733	635	595	629	2572
Pending (at the end of quarter)	1151	1229	1290	1324	1324
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance Team	394	324	233	450	450
Drug Diversion/Fraud	98	121	141	172	172
Probation/PRP	85	82	67	78	78
Mediation/Enforcement	74	14	8	28	28
Criminal Conviction	475	518	479	485	485
Application Investigations					
Received	181	217	151	244	793
Closed					
Approved	85	147	177	129	538
Denied	24	32	31	49	136
Total**	150	251	392	228	1021
Pending (at the end of quarter)	448	432	205	223	223
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	65	36	46	39	186
Citations Issued	308	253	192	290	1043
Citations Closed	339	358	290	185	1172
Total Fines Collected***	$336,840.00	$328,645.00	$298,395.00	$209,672.00	$1,173,552.00

* This figure does not include reports submitted to the supervisor.

** This figure includes withdrawn applications.

*** Fines collected (through 6/30/2011 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Fiscal Year 2010/2011

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	90	105	90	90	375
Pleadings Filed	83	65	55	102	305
Pending					
Pre-accusation	182	202	223	188	188
Post Accusation	255	268	241	258	257
Total*	508	496	516	520	520
Closed**					
Revocation					
Pharmacist	1	1	2	5	9
Pharmacy	0	0	0	0	0
Other	18	28	40	43	129
Revocation,stayed; suspension/probation					
Pharmacist	6	3	9	5	23
Pharmacy	0	0	0	0	0
Other	0	0	2	2	4
Revocation,stayed; probation					
Pharmacist	3	5	2	6	16
Pharmacy	1	1	6	1	9
Other	1	3	8	10	22
Suspension, stayed; probation					
Pharmacist	0	0	0	0	0
Pharmacy	0	0	0	0	0
Other	0	0	0	0	0
Surrender/Voluntary Surrender					
Pharmacist	2	1	2	1	6
Pharmacy	1	1	1	1	4
Other	12	8	6	9	35
Public Reproval/Reprimand					
Pharmacist	0	0	0	0	0
Pharmacy	0	0	0	0	0
Other	0	0	0	0	0
Cost Recovery Requested***	$108,566.50	$317,558.50	$449,152.25	$136,329.00	$1,011,606.20
Cost Recovery Collected***	$38,755.24	$74,313.04	$255,471.34	$53,990.59	$422,530.21

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2010/2011

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11

*** This figure includes administrative penalties

Board of Pharmacy Enforcement Statistics
Fiscal Year 2010/2011

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Probation Statistics					
Licenses on Probation					
Pharmacist	99	103	100	109	100
Pharmacy	8	11	15	19	15
Other	27	30	33	39	33
Probation Office Conferences	51	26	64	36	64
Probation Site Inspections	36	53	55	64	55
Probationers Referred to AG for non-compliance	1	0	5	3	9

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 6/30/2011)

Program Statistics					
In lieu of discipline	1	0	0	0	1
In addition to probation	3	3	0	4	10
Closed, successful	1	7	3	2	13
Closed, non-compliant	1	0	0	4	5
Closed, other	2	1	3	1	7
Total Board mandated Participants	45	55	45	56	56
Total Self-Referred Participants*	30	22	19	19	19
Treatment Contracts Reviewed	67	72	68	66	273

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of June 30, 2011

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 08/09	Total 09/10	Total 10/11
Complaints/Investigations			
Received	2545	2347	2425
Closed	1648	3909	2572
Pending (at the end of fiscal year)	2686	1033	1324
Cases Under Investigation (by Team) at end of fiscal year*			
Compliance	491	574	450
Drug Diversion/Fraud	183	103	172
Probation/PRP	244	102	78
Mediation/Enforcement	176	77	75
Criminal Conviction	1644	590	524
Application Investigations			
Received	372	847	798
Closed			
Approved	178	558	538
Denied	58	100	136
Total**	285	769	1021
Pending (at the end of quarter)	345	423	223
Letter of Admonishment (LOA) / Citation & Fine			
LOAs Issued	100	362	186
Issued	965	1827	1043
Abated	1064	1466	1172
Total Fines Collected ***	$115,152.50	$1,330,140.00	$1,173,552.00

* This figure does not include cases that have been submitted to the supervisor.

** This figure includes withdrawn applications.

*** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 08/09	Total 09/10	Total 10/11
Administrative Cases (by effective date of decision)			
Referred to AG's Office*	207	354	375
Pleadings Filed	125	272	305
Pending			
Pre-accusation	137	185	188
Post Accusation	106	281	257
Total *	274	433	520
Closed**			
Revocation			
Pharmacist	6	15	9
Pharmacy	4	2	0
Other	21	69	129
Revocation,stayed; suspension/probation			
Pharmacist	9	11	23
Pharmacy	0	5	0
Other	0	1	4
Revocation,stayed; probation			
Pharmacist	14	9	16
Pharmacy	1	1	9
Other	4	7	22
Suspension, stayed; probation			
Pharmacist	0	0	0
Pharmacy	0	0	0
Other	0	0	0
Surrender/Voluntary Surrender			
Pharmacist	3	9	6
Pharmacy	1	5	4
Other	7	17	35
Public Reproval/Reprimand			
Pharmacist	0	1	0
Pharmacy	0	0	0
Other	0	1	0
Cost Recovery Requested	$147,025.00	$312,840.75	$1,011,606.20
Cost Recovery Collected	$128,230.64	$335,420.58	$422,530.21

* This figure includes citation appeals

** This figure includes cases withdrawn

*** This figure included adminstrative penalties

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 08/09	Total 09/10	Total 10/11
Probation Statistics			
Licenses on Probation			
Pharmacist	110	101	90
Pharmacy	4	8	4
Other	12	29	14
Probation Office Conferences	48	98	40
Probation Site Inspections	153	110	163
Probationers Referred to AG for non-compliance	5	13	7

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program

Program Statistics			
In lieu of discipline	3	1	2
In addition to probation	9	6	10
Closed, successful	15	11	5
Closed, non-compliant	2	4	3
Closed, other	6	14	1
Total Board mandated Participants	58	47	49
Total Self-Referred Participants*	21	29	23
Treatment Contracts Reviewed	206	201	126

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.